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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,449	07/31/2003	Stefan A. Sharpe	PD01505	4692

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
NGUYEN, SANG H	
ART UNIT	**PAPER NUMBER**
2877	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H.A.

Office Action Summary	Application No.	Applicant(s)	
	10/633,449	SHARPE ET AL.	
	Examiner	Art Unit	
	Sang Nguyen	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9* is/are rejected.

7)☒ Claim(s) *4-8 and 10-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a **smoothness index of a metered dose container**" in claims 1 and 2; the " **an inner core**" in claims 1-2; the "**reflected light photomicrography**" in claims 1-2; the "**a digital image containing a plurality of pixel of the inner core**" in claims 1-2 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al (WO 93/12615) in view of MacRae et al (UI.S. Patent No. 6,644,305).

Regarding claims 1-3; Martin et al discloses a method for determining a smoothness surface of a sample comprising the steps of:

a) subjecting the surface smoothness of the sample (figure 1) to reflected light photomicrography to a camera (figure 1) to obtain a digital image (page 2 line 15) containing a plurality of pixels of said surface sample (page 3 lines 10-31), wherein the darkness pixel is corresponds 0 and the brightness pixel corresponds 1 (page 5 lines 17-22);

b) determining from said digital image the brightness of each of said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness (page 5 lines 23-35), and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said surface sample page 3 lines 1-8 and page 6 lines 1-32). See figure 1-3.

Martin et al discloses all of features of claimed invention except for an inner core of a metered dose container having at least one pharmacologically active agent is a corticosteroid. However, MacRae et al teaches that it is known in the art to provide a nasal inhaler comprises an inner core of a metered dose container (440 of figure 22 and col.7 lines 55-65 and col.14 lines 54-60) having at least one pharmacologically active agent is a corticosteroid (col.10 lines 40-65 and col.1 lines 9-45). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine a method for determining a smoothness surface of a sample of Martin et al with an inner core of a metered dose container having at least one pharmacologically active agent is a corticosteroid as taught by MacRae et al for the purpose of delivery of substances aimed at treating upper respiratory ailments such as sinusitis, allergic conditions.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al in view of MacRea et al as applied to claim 2 above, and further in view of Van Oort et al (U.S. 2003/0005927).

Regarding claim 9; Martin et al in view of MacRea et al teaches all of features of claimed invention except for at least one pharmacologically active agent is a β-agonist. However, Van Oort et al teaches that it is known in the art to provide at least one pharmacologically active agent is a β-agonist (claim 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine a method for determining a smoothness surface of a sample of Martin et al with at least one pharmacologically active agent is a β-agonist as taught by MacRae et al for the purpose of delivery of substances aimed at treating upper respiratory ailments such as sinusitis, allergic conditions.

Allowable Subject Matter

Claims 4-8 and 10-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record, taken alone or in combination, fails discloses or render obvious a method for determining a smoothness index of a metered dose container comprising all the specific elements with the specific combination including of *the codicosteroid is selected from the group consisting of mometasone furoate anhydrous; beclomethasone dipropionate; budesonide; fluticasone; dexamethasone; flunisolide; triamcinolone; (22R)-6α, 9α-difluoro-11β ,21-dihydroxy-16α,17α-propylmethylenedioxy-4-pregnen-3jzo-dione; and tipredane* in set forth of claim 4;

The prior art of record, taken alone or in combination, fails discloses or render obvious a method for determining a smoothness index of a metered dose container comprising all the specific elements with the specific combination including of *the β-agonist is selected from the group consisting of albuterol, terbutaline, salmeterol, bitolterol, formoterol, eFormoterol, 2(1H)-Quinolinone, 8-hydroxy-5-[1-hydroxy-2-l[[2-(4-(methoxyphenyl)-1-methylethyl] aminolethyl]-monohydrochloride, [R-(R*,R*)]-*in set forth of claim 10;

The prior art of record, taken alone or in combination, fails discloses or render obvious a method for determining a smoothness index of a metered dose container comprising all the specific elements with the specific combination including of *the at least one pharmacologically active agent is selected from the group consisting of ipratropium bromide, oxitropium bromide, sodium cromoglycate, nedocromil sodium, montelukast, zafirlukast, pranlukast, bambuterol, fenoterol, clenbuterol, procaterol and broxaterol* in set forth of claim 15; and

The prior art of record, taken alone or in combination, fails discloses or render obvious a method for determining a smoothness index of a metered dose container comprising all the specific elements with the specific combination including of *at least one pharmacologically active agent is selected from a combination of a codicosteroid and a β-agonist* in set forth of claim 17.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Scialdone et al (6815426) discloses angiogenesis-inhibitory

tripeptides, compositions; Blakley (6691058) discloses determination of pharmaceutical expiration date; Jeweet et al (6223,746) discloses metered dose inhaler pump; or Scholz et al (6132835) discloses composite casting tape.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang Nguyen whose telephone number is (571) 272-2425. The examiner can normally be reached on 9:30 am to 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SN

Sang Nguyen/SN

July 21, 2005

HWA (ANDREW) LEE
PRIMARY EXAMINER